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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,926	01/30/2001	Claus Frohberg	514413-3865	6519

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FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER
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KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

12

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/744,926

Applicant(s)

FROHBERG, CLAUS

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-42 is/are pending in the application.
- 4a) Of the above claim(s) 27,34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s)    is/are allowed.
- 6) ☒ Claim(s) 26,28-33 and 36-41 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s)    are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on    is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on    is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No.   .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s)
- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26-42 are pending. Claims 27 and 34-35 are withdrawn from consideration. Claim 42 is newly added. Claims 26, 28-33, 36-42 are examined.

Claim 36 was inadvertently omitted from the rejections in the previous Office Action of 10/03/2002 and is included in the rejections below.

Rejection of Claims 26, 28-33, and 37-41 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments and arguments.

#### ***Claim Rejections - 35 USC § 112***

Claims 26, 28-33, and 37-41 remain and Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/03/2002. Applicant's arguments filed 4/09/2003 have been considered but are not deemed persuasive.

Applicant asserts they have provided relevant structural characteristics in the form of a nucleotide sequence encoding an alpha-glucosidase demonstrating a correlation between structure and function, and that a limitation to only the nucleotide sequence of SEQ ID NO: 1 would unfairly narrow the scope of the invention (response page 4 lines 1-12). The Examiner acknowledges Applicant's claim to a broader scope for the invention with respect to written description. However, Applicant has not taught other sequences that would function in the same

Art Unit: 1638

manner as SEQ ID NO: 1, and a claim encompassing the broad genus of 70% homology is not supported by the specification. A claim to 85% sequence identity to SEQ ID NO: 1 would better approximate the limited scope of the specification. Further, Applicant has recited incomplete hybridization conditions in Claim 31 that do not meet the Written Description Guidelines.

Amendment of Claim 26 to recite over 85% sequence identity instead of 70% sequence identity, cancellation of Claim 42, and amending Claim 31 to include both a temperature of 65 degrees celcius and salt concentrations of 0.1X SSC would obviate the written description rejection.

Claims 26, 28-33 and 37-41 remain and Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule of SEQ ID NO: 1 or one over 85% similar thereto encoding a protein with the function of a potato  $\alpha$ -glucosidase of SEQ ID NO: 2, does not reasonably provide enablement for nucleic acid molecules that encompass SEQ ID NO: 1 or its derivatives or parts, and nucleic acid molecules that specifically hybridize with, are complementary to, deviate from, and have more than 70% homology than said nucleic acid molecules, antisense of said molecule, a vector comprising said nucleic acid molecule, host cell comprising said vector, a method for making a transgenic plant with modified starch using said vector comprising said nucleic acid molecule integrated into the plant genome, and transgenic plant cells and plants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/03/2002. Applicant's arguments filed 4/09/2003 have been considered but are not deemed persuasive.

Applicant asserts that the claims should be limited to materials that will work or meet the guidelines specified for preferred materials in a process (response page 4, lines 20-21) and that because Claim 26 recites both structure and function undue experimentation would not be required to reach a nucleic acid molecule covered by Claim 26 (response page 4, lines 25-27). The specification provides no guidance for sequences having as low as 70% sequence identity when there are no other representative sequences taught in the specification to support the breadth of the claim. Further, as indicated above the hybridization conditions recited in Claim 31 are incomplete. Given the limited guidance in the specification for isolated polynucleotides having 70% sequence identity that would function as a potato alpha-glucosidase, as well as unpredictability set forth previously, the invention is not enabled for the full scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28-33 and 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 26 and throughout the claims, "homology" should be replaced by --sequence identity--.

At Claim 28 and throughout the claims "a nucleic acid molecule as claimed in Claim 26" should be replaced by --the nucleic acid molecule as claimed in Claim 26-- whenever it is dependent from another claim (See Claims 28-33 and 36-39).

Art Unit: 1638

At Claim 36, "ensure transcription and synthesis of an RNA, which is optionally translatable, in a pro- or eukaryotic cell" should be changed to --that initiate transcription of RNA in a cell--.

At Claim 37, lines 1 and 2, change "a nucleic acid" and "a vector" to --the nucleic acid-- and --the vector--.

At Claim 37, line 2, "Claim 32" should be --Claim 32,--.

At Claim 37, please add to end of the claim, --and which comprises said nucleic acid molecule or vector--.

At Claim 38, "a process for the generation of a transgenic plant cell" should be changed to --a method for making a transgenic plant cell--, and "a vector" should be changed to --the vector--.

At Claim 39, the claim should be changed to read --a plant cell made by the method of Claim 38--.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26, 28, 30, 31 and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The DNA of Claim 26, since it has not been isolated by the hand of man reads as a product of nature, thus falling outside the five classes of patentable subject matter. The derived host cell of Claim 37 may not contain the introduced DNA, and so would be indistinguishable from a naturally occurring cell.

Art Unit: 1638

The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Amendment of Claim 26 to replace "A" with --An isolated-- would obviate this rejection.

Amendment of Claim 37 as indicated above would obviate this rejection.

Claims 26, 28-33, and 36-41 are rejected.

Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 26, 28-33, and 36-42 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1 and plants transformed with said polynucleotide.

No Claim is allowed.

Application/Control Number: 09/744,926  
Art Unit: 1638

Page 7

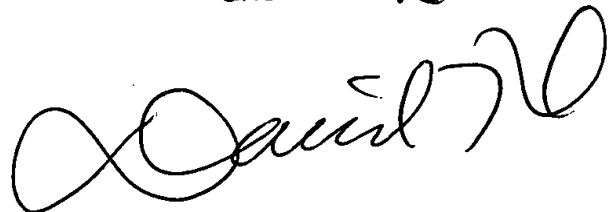
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Russell Kallis  
June 28, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a large, stylized flourish at the end.